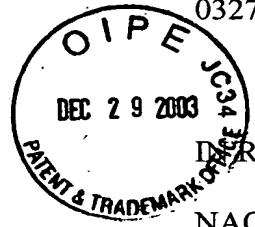


0327-0759-0



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

:

NAOKO TSUJI ET AL.

: GROUP ART UNIT: 1651

SERIAL NO: 09/220,691

:

FILED: DECEMBER 28, 1998

: EXAMINER: WEBER

FOR: METHOD OF INHIBITING HAIR GROWTH

APPEAL BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Appellants appeal the final rejection of Claims 1, 3, 6 and 22 of the above-identified application as set forth in the Advisory Action dated July 28, 2003.

I. REAL PARTY IN INTEREST

The real party in interest is Kao Corporation by virtue of the assignment executed on December 16, 1998. The executed assignment was filed in the U.S. Patent & Trademark Office on May 4, 2000, and is recorded beginning at Reel 010788, Frame 0313.

II. RELATED APPEALS AND INTERFERENCES

To the best of Appellants' undersigned representative's knowledge, there are no related interferences. The following is a list of pending appeals involving either the same real party in interest or similar subject matter:

U.S. Serial No. 09/341,706

U.S. Serial No. 09/468,777

Reexamination Control No. 90/005,740

III. STATUS OF CLAIMS

Claims 1, 3, 6 and 22 are pending in the above-identified application, upon entry of the accompanying amendment. All pending claims are appealed. The remainder of the claims have been cancelled either previously or with the accompanying amendment.

IV. STATUS OF AMENDMENTS

An amendment is submitted herewith in order to simplify the issues on appeal and to place the claims in better condition for this appeal. The amendment amends Claim 1 to remove the embodiment of a compound that is an inhibitor of neutral endopeptidase. Claim 22 is also amended to correct a spelling error.

V. SUMMARY OF INVENTION

The present invention relates to a method for inhibiting hair growth. (page 2, lines 23-27) The method comprises the topical application of an inhibitor of elastase-like enzymes. (page 4, lines 4-15) The compound is further required to not be a matrix metalloproteinase inhibitor (original claim 2) and is required to not be a mercaptopropionamide compound. (exclusion of one embodiment listed on pages 7-9).

VI. ISSUES

There is one issue in this appeal as follows:

Does the specification provide enablement under 35 U.S.C. 112, first paragraph for the scope of the present pending claims?

There are no other rejections of the claims.

VII. GROUPING OF CLAIMS

Claims 1, 3, and 6 stand or fall together. Claim 22 will be argued in a separate paragraph below.

VIII. ARGUMENTS AGAINST THE REJECTION OF CLAIMS 1, 3, AND 6 UNDER 35 U.S.C. 112, FIRST PARAGRAPH

The present application clearly provides an enabling disclosure with respect to claims 1, 3 and 6 that would permit one of ordinary skill in the art to practice the invention without undue experimentation. The invention as claimed in claim 1 is a method for the inhibition of hair growth, which involves application of a compound to a subject in need thereof. This step of the method is clearly enabled as the specification describes various modes of application at pages 10-11. The compound used in the present invention method is required to have three qualities: 1) it must be an inhibitor of elastase-like enzymes; 2) it does not inhibit matrix metalloproteinase and 3) it is not a mercaptopropionamide.

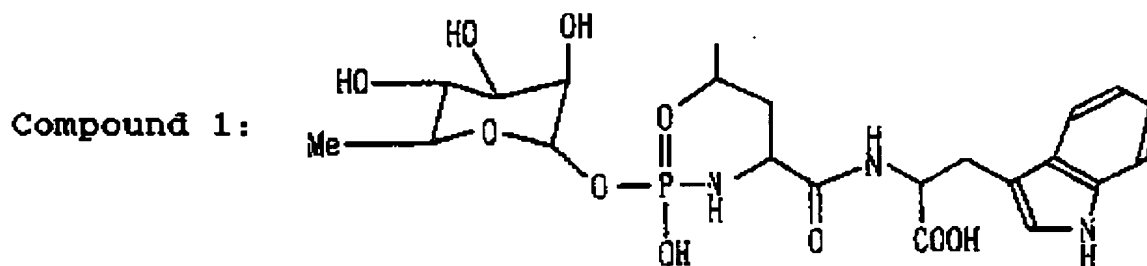
Enablement is a question of law based upon underlying factual inquiries.¹ The enablement requirement is met if the description enables any mode of making and using the claimed invention.² Accordingly, a first test for enablement is whether there is any mode of

¹ See for example, *BioTechnology General Corp. v. Genentech, Inc.*, 267 F.3d 1325, 60 U.S.P.Q.2d 1430 (Fed. Cir. 2001).

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the invention that is provided and described in the specification. In this case, Applicants have pointed out Compound 1 in the Examples section of the application as falling within the claimed invention. This

compound:



is shown in the specification at Table 1, page 14 to inhibit elastase activity. Further Applicants have previously noted in a response that it has been also determined to not inhibit MMP activity. This result is supported by the concurrently filed Rule 1.132 Declaration, in which the results of the MMP activity test are specifically reported. Further, this compound has been found to inhibit hair growth, as shown in Table 3, page 18. Lastly, it is clearly not a mercaptopropionamide, since it contains no mercapto (SH) group. (Appellants note that a mercaptopropionamide is a compound such as Compounds 7 and 8).

Additionally, Appellants note that Compound 1 is part of a class of compounds known as phosphonic acid derivatives, more specifically phosphoramidates, of which compounds 2-6 are also members. This is one of the classes of compounds mentioned in the application (see page 5 et seq).

In the Advisory Action, the Examiner appears to have interpreted Appellants arguments about the disclosure of the phosphoramidates as an attempt to read limitations from the specification into the claims. Nothing could be farther from Appellants intent. Appellants have only mentioned the phosphoramidates specifically, as one example of the

compounds covered by the claims, and as an example provided in the application for enablement purposes.

In order to practice the present invention, one of ordinary skill merely needs to turn to the various known non-mercaptopropionamide elastase inhibitory compounds, examples of which have been provided by many of the references cited by the Examiner which note elastase inhibitors, as well as the fact that those of ordinary skill in the art are well familiar with many compounds having elastase inhibitory activity. The only question at that point is whether the compound has MMP inhibitory activity or not. This is readily determined using commercially available assays well known to those of skill in the art, as exemplified in the accompanying Rule 1.132 Declaration.

The Examiner appears to take the position that Appellants must provide not just guidance, but must identify the various compounds or compound classes specifically in order to enable a broad claim scope. This is contrary to the case law however.

In re Wright, 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993) states: “Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation’....*Nothing more than objective enablement is required*, and therefore it is *irrelevant whether this teaching is provided through broad terminology or illustrative examples.*” (emphasis added)

Further as noted in the previous response, the Federal Circuit in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986) noted that enablement is not precluded even if some experimentation is required. In that case, the patented claims were drawn to an assay that used monoclonal antibodies that were identified only by their affinity for an unspecified antigenic substance. This is basically the case in the present claims: the

compound used in the method of the present invention is identified by its elastase-like enzyme inhibitory activity, its lack of MMP inhibitory activity, and the fact that it is not a mercaptopropionamide. At issue in the *Hybritech* case was whether the screening process necessary to test the necessary characteristics of the monoclonal antibodies produced was undue experimentation. Even though the monoclonal antibody production process produced a large multitude of species in an array, each of which would necessarily have to be screened, the Court held that since the screening process was well known in the art, there was no undue experimentation needed to practice the invention. This was even in light of the absence of any identification in the claim of the antigenic substance for which affinity of the monoclonal antibody was being tested!

The present claimed invention is very similar. The compound needed to practice the invention is not specifically identified in the claim, except by its activity with respect to elastase-like enzyme inhibition and MMP non-inhibition. Accordingly, one of skill in the art would have to screen a compound at most through two enzyme activity assays (if one started with a known elastase inhibitor, only one screen would be required). As such, how can this be different from *Hybritech*, particularly when some guidance on preferred embodiments is provided in the specification with respect to the phosphoramidates?

The Examiner continues to rely on the *Wands* case (*In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed.Cir. 1988)). The Examiner further delves into a long discussion in the Advisory Action with respect to enzyme active sites and structure-activity-relationships. However, when the enzyme activities are readily susceptible to commercially available assays that are well known in the art, and there is guidance provided both by discussion of one class of compounds in the specification, and the wealth of known elastase inhibitors in the art, it can hardly be seen as undue experimentation to have to test the compound for enzyme activity

to determine whether it falls within the claims or not. The standard of “undue experimentation” was discussed by the court in *Ex parte Forman*, 230 U.S.P.Q. 546, 547 (1986) stating the following:

“The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art: *Ansul Co. v. Uniroyal, Inc.* [169 U.S.P.Q. 759, 762 (2d Cir. 1971)]”

The “nature of the invention” was more particularly discussed in the cited *Ansul* decision. In *Ansul* the court explained that inventors that discover a “new use for existing composition” are entitled to broad, generic claims even if the inventors have not disclosed every potential embodiment of the invention (see 169 U.S.P.Q. at 762). With respect to the present invention, this means that Appellants are not required to disclose and test every elastase inhibitor to determine if it lacks MMP inhibition in order to be entitled to a generic patent. The present invention is not to the compounds having the required activities themselves. Rather, as in both *Ansul* and *Hybritech*, Appellants have discovered a new use (reduced hair growth) for compounds (elastase inhibitors which do not inhibit MMP) that are known. Similar types of generic claims have been permitted, even in U.S. 5,962,466 (*Styczynski et al*), of record in the present case. That patent claims generically a method for reducing hair growth using MMP inhibitors, but does not specify the inhibitors themselves in the generic claim. Appellants are the first to recognize that one can use an elastase inhibitor that does not inhibit MMP, in order to inhibit hair growth.

Further, a person of ordinary skill would have to perform very little experimentation to practice the present invention. Given a particular compound, it is very easy to determine if the compound has elastase inhibitory activity, then to determine if it does not have MMP

inhibitory activity. These two tests are well known in the art and readily available. If the person of ordinary skill starts with a known elastase inhibitor, there is only need of one test, that of MMP inhibition. As such, there is little experimentation necessary to practice the invention.

In the present application, the prior art (Styczynski) actually teaches a connection between having MMP inhibition and hair growth inhibition. However, nothing is stated about the ability to use a compound that inhibits elastase, but does not have MMP inhibition activity. The invention is therefore of pioneer status and entitled to broad protection.

The chemical/biochemical arts are generally unpredictable. However, now that Appellants have disclosed their invention, it is predictable that inhibitors of elastase that do not have MMP inhibitory activity, when applied topically will work to reduce hair growth.

Appellants claims, although broad, cover no more than Appellants contribution, the use of inhibitors of elastase that do not inhibit MMP to reduce hair growth.

Accordingly, in accordance with *In re Wright*, *In re Ansul* and *In re Wands*, Appellants are entitled to broad claims given objective enablement, even if provided by broad terminology. Also, Appellants have provided at least one specific example as enabling of the claims, in accordance with *Engel v. Lockformer* (supra). Since it is not required to provide specific examples to enable every mode of practicing the invention, Appellants assert that the Examiner's rejection under 35 U.S.C. 112, first paragraph is improper and should be reversed.

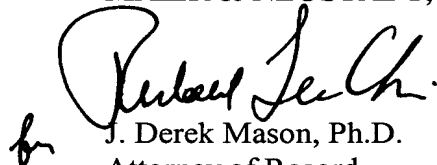
ARGUMENT AGAINST THE REJECTION OF CLAIM 22 UNDER 35 U.S.C. § 112 FIRST
PARAGRAPH

In addition to the arguments set forth for the patentability of Claims 1, 3, and 6 in the section above, Claim 22 sets forth a specific class of compounds, namely the phosphonic acid compounds, and derivative and salts thereof, which can be used in the present invention. While the Examiner has previously objected to this claim over various references showing a variety of phosphonic acid derivatives that are MMP inhibitors, and thus as including non-operative embodiments, Appellants note that one of ordinary skill in the art would know that those compounds are not a part of the claim by the very fact that they are known MMP inhibitors. Again, Appellants have provided a claim that can be readily practiced, and the bounds of which can be readily determined, merely by the performance of zero, one or two assays, depending on the known properties of the compound in question. As such, this more limited claim provides even more guidance as to the compounds useful in the invention. Accordingly, given the arguments above and the more limited scope of Claim 22, Appellants note that the Examiner's position is unsustainable and should be reversed.

In view of the preceding arguments Appellants respectfully request that the Examiner's rejections of Claims 1, 3, 6 and 22 be reversed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.


for J. Derek Mason, Ph.D.
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APPENDIX

Pending claims on appeal in U.S. Application 09/220,691 (as amended in accompanying amendment):

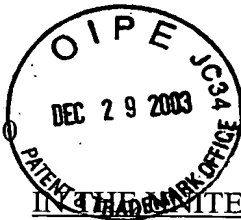
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3. The method according to claim 1, wherein the inhibitor of elastase-like enzymes is an inhibitor of an elastase-like enzyme derived from a dermoepidermal fibroblast.

6. The method according to claim 1, wherein said subject is a human.

22. The method of claim 1, wherein said inhibitor of elastase-like enzymes is a phosphonic acid compound, or a derivative or salt thereof.--

0327-0759-0



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :
NAOKO TSUJI ET AL. : GROUP ART UNIT: 1651
SERIAL NO: 09/220,691 :
FILED: DECEMBER 28, 1998 : EXAMINER: WEBER

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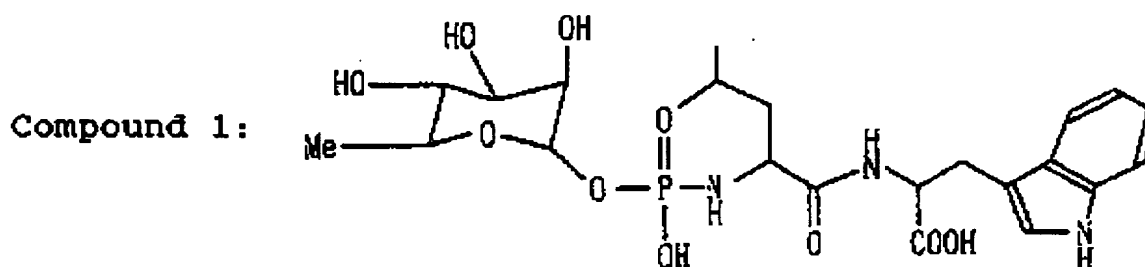
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Further, a person of ordinary skill would have to perform very little experimentation to practice the present invention. Given a particular compound, it is very easy to determine if the compound has elastase inhibitory activity, then to determine if it does not have MMP

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In the present application, the prior art (Styczynski) actually teaches a connection between having MMP inhibition and hair growth inhibition. However, nothing is stated about the ability to use a compound that inhibits elastase, but does not have MMP inhibition activity. The invention is therefore of pioneer status and entitled to broad protection.

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Appellants claims, although broad, cover no more than Appellants contribution, the use of inhibitors of elastase that do not inhibit MMP to reduce hair growth.

Accordingly, in accordance with *In re Wright*, *In re Ansul* and *In re Wands*, Appellants are entitled to broad claims given objective enablement, even if provided by broad terminology. Also, Appellants have provided at least one specific example as enabling of the claims, in accordance with *Engel v. Lockformer* (supra). Since it is not required to provide specific examples to enable every mode of practicing the invention, Appellants assert that the Examiner's rejection under 35 U.S.C. 112, first paragraph is improper and should be reversed.

ARGUMENT AGAINST THE REJECTION OF CLAIM 22 UNDER 35 U.S.C. § 112 FIRST

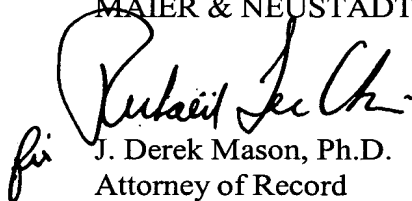
PARAGRAPH

In addition to the arguments set forth for the patentability of Claims 1, 3, and 6 in the section above, Claim 22 sets forth a specific class of compounds, namely the phosphonic acid compounds, and derivative and salts thereof, which can be used in the present invention. While the Examiner has previously objected to this claim over various references showing a variety of phosphonic acid derivatives that are MMP inhibitors, and thus as including non-operative embodiments, Appellants note that one of ordinary skill in the art would know that those compounds are not a part of the claim by the very fact that they are known MMP inhibitors. Again, Appellants have provided a claim that can be readily practiced, and the bounds of which can be readily determined, merely by the performance of zero, one or two assays, depending on the known properties of the compound in question. As such, this more limited claim provides even more guidance as to the compounds useful in the invention. Accordingly, given the arguments above and the more limited scope of Claim 22, Appellants note that the Examiner's position is unsustainable and should be reversed.

In view of the preceding arguments Appellants respectfully request that the Examiner's rejections of Claims 1, 3, 6 and 22 be reversed.

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APPENDIX

Pending claims on appeal in U.S. Application 09/220,691 (as amended in accompanying amendment):

--1. A method of inhibiting hair growth, which comprises topically administering to an affected area of a subject in need thereof an inhibitor of elastase-like enzymes, wherein said inhibitor of elastase-like enzymes is not a matrix metalloproteinase inhibitor, and wherein said inhibitor of elastase-like enzymes is not a mercaptopropionamide compound.

3. The method according to claim 1, wherein the inhibitor of elastase-like enzymes is an inhibitor of an elastase-like enzyme derived from a dermoepidermal fibroblast.

6. The method according to claim 1, wherein said subject is a human.

22. The method of claim 1, wherein said inhibitor of elastase-like enzymes is a phosphonic acid compound, or a derivative or salt thereof.--